

Legal Issues in Bone Marrow Transplantation

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The article discusses some of the more common legal issues involved in bone marrow transplantation. These include malpractice claims, testing prospective donors for AIDS, sale of bone marrow, informed consent for both donor and recipient, and questions that arise when the donor is a child.

Legal problems involved in organ transplantation are few and far between [1]. The number of cases involving any sort of issue about transplantation is far fewer than one might expect from the numbers of cases involving most other aspects of health care delivery.

MALPRACTICE

Medical malpractice actions involving any sort of transplantation are extremely rare [2]. There are none that can be located involving bone marrow transplantation. Three or four in all the United States involve malpractice actions by kidney donors, all of whom seem to have developed serious complications (such as life-threatening infections) following removal of their kidneys [3]. A few recipients of kidneys and eyes have brought malpractice actions, but, given the number of transplants and the incidence of malpractice suits in other types of medical care, the numbers are still far below what one would expect to find. One case [4] involved a plaintiff who had received a corneal transplant from a patient who had died of an infection. The plaintiff, who went completely blind following the surgery, proved that the hospital where the cornea was harvested had done virtually nothing to screen donors. Expert testimony was presented and not contradicted that patients with some specific diseases should never be accepted as organ donors; the dead patient from whom the cornea had been removed had more than one of those diseases. The resident who removed the eyes had no idea of the cause of death and had no information about the patient's medical history. The hospital was found liable. Of course a donor (of blood or anything else) must be appropriately screened, and failure to do so is negligence.

AIDS

Nowadays, of course, the issue of screening donors usually involves questions of screening for AIDS. Connecticut has enacted a statute [5] requiring informed consent to HIV testing, confidentiality of HIV-related information and pre- and post-test counseling. An exception to the consent requirement is found in Section 2e (2) when the testing is "in relation to the procuring, processing, distributing or use of a human

body or human body part” for research, therapy, or for transplantation. If consent is obtained, however, counseling must be provided.

There is probably no excuse, however, for failing to tell a living donor—whether it be of blood, bone marrow, sperm, ova, or other tissue or fluid—that HIV testing will be done. Prospective donors may change their minds once they reflect on the social and economic consequences of a positive test result that will appear on whatever medical record they will have accumulated at the institution at which they would have donated. No federally funded clinical research that requires screening for AIDS may omit informing prospective subjects that they will be screened [6]. If the transplantation program receives federal funding, regardless of any exemptions under state law, compliance with federal regulations is required.

A situation to which health professionals who counsel potential donors must be particularly sensitive is the situation in which a prospective donor, a family member of a critically ill person, is in a risk group about which the rest of the family does not know. There may be subtle and sometimes not-so-subtle pressure on everyone in the family to be tested for compatibility, and the person may be afraid to speak up about why he or she could be HIV-positive. Plausible and uninformative reasons to be given to the rest of the family for not accepting as a donor the person who does not wish to have AIDS testing should be devised in advance of such a situation.

SALE OF BONE MARROW

Although the sale of organs has been a serious concern of lawyers and ethicists for many years [7], many authorities felt that the obvious exploitation of the desperately poor which could result if people were allowed to sell their kidneys was not present in the sale of a “replenishable” organ such as blood. Bone marrow is, of course, replenishable, but the National Organ Transplant Act [8] includes bone marrow in the list of organs which one may not buy or sell in interstate commerce [9]. The penalty for such purchase or transfer includes a fine of not more than \$50,000 or imprisonment for not more than five years or both.

Since the National Organ Transplant Act only applies when interstate commerce is involved, it is not relevant to a transaction between two residents of the state in which the transplant occurs. Probably it would not apply either to a situation in which a person from another state came to a transplant center to provide the bone marrow and the packaged marrow did not cross a state line. Some states have enacted their own statutes to prohibit intrastate sale of organs [10]; these may or may not include bone marrow.

INFORMED CONSENT

The doctrine of informed consent requires that any patient be sufficiently informed about contemplated medical procedures so that he or she may make an intelligent and autonomous decision to have or to refuse an intervention [11]. The necessity for disclosure increases as the gravity of the patient’s condition decreases—if a patient is critically ill and there is only one possible therapy, as long as the physician has been told by the patient to “do everything,” the need for detailed discussion diminishes. On the other hand, a patient who presents for cosmetic surgery must know all the possible risks and alternatives in some detail.

Informing a patient about an elective procedure includes a discussion of the procedure and what it entails in terms of discomfort, length of time in the hospital, size

of scars, and all other information the "reasonable person" would want to know. Risks must be spelled out, although which risks are qualitatively and quantitatively sufficient to demand disclosure is not always easy to determine. Benefits (if any) must also be explained. In the case of a healthy donor, of course, the benefit is psychic, not physical. Alternatives (if any) must also be presented, along with the risks and benefits of each.

Any donor, of course, is a healthy individual who will derive no medical benefit from the donation. He or she, therefore, must be told about all known risks and, in detail, what to expect. When the donor is a competent adult, this discussion is usually not a problem. The patient, too, must give informed consent to receiving the transplant and, it seems, a part of the consent process in these cases is a frank discussion of the economics involved, both short-term and long-term. Some insurance companies and HMOs cover transplantation, other do not, and the patient may prefer to forego the procedure rather than to have his or her family saddled with debt even if the procedure is likely to be successful.

CHILDREN AS DONORS

If a minor is going to be a kidney donor, it is customary to ask for a court order approving the donation [12]. Almost all courts have granted these orders, based on the idea that the donor child derives benefit from the continued life of the sick sibling. The courts' theory is that a child derives more benefit from a happy home and the sibling relationship than he or she would from growing up with two kidneys [13]. Other courts have dispensed with this concept of benefit and have simply found that parents are allowed to consent to donation by one healthy child to a sick child on the basis of a familial cost-benefit analysis [14].

The Louisiana courts, however, refused to permit a severely retarded minor, whose capacity for relationships was marginal at best, to donate a kidney for his adult sister. The reasoning was that it would make very little difference to the boy if his sister was alive or dead [15].

The reason that court orders have been requested is that parents who are torn between the welfare of a critically ill child and one who is well are not in a position to give an objective consent to putting the donor child at risk. Not only does removal of a kidney involve risk, but there is some risk inherent in the donor's going through life with one kidney.

Since bone marrow regenerates, however, the long-term risks are entirely different from the issues present in kidney donations by minors. As far as can be determined, lawyers for institutions in which bone marrow transplants are done see no reason to ask for court permission in these cases. That conclusion assumes, however, that a child who is old enough to discuss and understand the donation procedure but who objects to being a donor is not coerced into agreeing to the procedure. Although there might be circumstances, although difficult to envision, under which it would be appropriate to draft one child in the family, over his or her objections, to save the life of a sibling, in the face of objection by the donor, most lawyers would insist on a court order to protect both the physician and the institution from actions for assault and battery when the donor comes of age. The likelihood that a court would order an unwilling young person to serve as a bone marrow donor when it is clear that no adult can be so compelled is quite small.

Since an adolescent, even though a minor, may very well understand as much as an

adult about donation but minors as a class of persons cannot give a legally valid "consent," we speak of the adolescent's agreement as "assent."

If the child is too young to understand the procedure, as with any other medical decision, the parents would have the authority to consent.

An adult may refuse treatment even if death is a certain result [16]. If a parent refuses life-saving therapy for a minor (such as a Jehovah's Witness who is refusing a blood transfusion for her toddler who has been hit by a car), courts routinely order such medical care to be given [17]. As far as can be determined, no court anywhere in this country, Canada, or Great Britain has ever refused to order blood transfusions requested by the child's physician, and most other forms of therapy designed to save a child's life or prevent serious disability are almost always ordered as well.

Court-ordered donations are, however, another question entirely. This issue has been raised at least once in a situation in Washington State. The Child Welfare Department considered trying to obtain a court order to require parents of a three-year-old to have him tested to see if he could be a bone marrow donor for his seven-year-old sister. The parents had decided that they did not wish to subject their young son to the procedure and therefore there was no need to have him tested for compatibility. The Child Welfare Department's lawyer advised them that such an attempt would be futile, so the matter was dropped.

Several cases have dealt with adults who have attempted to force their relatives to be tested for bone marrow compatibility [18]. In all of them, the courts held that the word "donation" means "gift" and that one cannot obtain court orders to compel gifts. The courts also pointed out that no one's body can be used compulsorily for the benefit of another.

In one famous case from Iowa [19], a man who was close to death and could not find a bone marrow donor discovered from an employee at the University of Iowa Registry that somewhere, according to their records, existed a woman who apparently would be a perfect match. She had been typed because her son needed bone marrow. When the Registry contacted her on two occasions and asked if she would be willing to be a donor for this unrelated patient, she declined. The man then sued to compel the Director of the Registry to release her name and address so that he (the patient) could contact her directly and beg for her help. Both the trial judge and the Supreme Court of Iowa held that release of a donor's name and address without her consent would be an invasion of her privacy, and thus the patient had no right to this information.

Moreover, in any procedure covered by federal regulations for human subjects research, informed consent requirements state that the prospective subject has the right to refuse to participate [20] without loss of benefits to which he or she is otherwise entitled. No court, therefore, has the authority to compel such participation, and no physician may make future medical care contingent on "cooperation" with the donation. If adults cannot be compelled by courts to be donors, even for their own children, it is even less likely that a parent's refusal to permit his child to be a donor would ever be overridden by a court.

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20. 45 Code of Federal Regulations, Part 46, Section 116 (8)